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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,116	09/10/2003	Daniel M. Lafontaine	10527-429004	3548
26191	7590	07/05/2005	EXAMINER	
FISH & RICHARDSON P.C. PO BOX 1022 MINNEAPOLIS, MN 55440-1022			GIBSON, ROY DEAN	
		ART UNIT	PAPER NUMBER	
		3739		

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/659,116	LAFONTAINE, DANIEL M.
Examiner	Art Unit	
Roy D. Gibson	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 18 May 2005.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 28,30-32 and 36-41 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 28,32 and 37-41 is/are rejected.

7) Claim(s) 30,31 and 36 is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1)  Notice of References Cited (PTO-892)

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5/10/2004.

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Objections*

Claim 37 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 37 recites the same limitation as claim 32 from which it depends, thus not further limiting claim 32.

### **Claim Rejections - 35 U.S.C. § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 38 recites the limitation "the lesion" in line 7. There is a lack of proper antecedent basis for this limitation in the claim. The examiner suggests "the lesion" be replaced with "the tissue" to correct this.

### **Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 28 and 38-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Friedman et al. (5,147,355). Friedman et al. disclose a cryo-therapy device and its method of use comprising:

a shaft (12) having a proximal and distal end;

a cooling chamber (volume adjacent to the expansion orifice 34) disposed at the distal end of the shaft defining an interior space (Figure 2);

a coolant intake tube (22) disposed within the shaft and having a distal opening in fluid communication with the interior space of the cooling chamber and arranged to create a phase change in fluids (liquid to gas) introduced through the intake tube, and

an exhaust tube (24) disposed within the shaft and having a distal opening in fluid communication with the interior space of the cooling chamber (Figure 1 and col. 3, lines 12-61).

The method of use is disclosed essentially as claimed (col. 3, line 21-col. 4, line 31 and claims 1-6) whereby the minimum temperature can be controlled to about -60°C and thus freezing a portion of the tissue. A range of minimum temperatures can be provided depending upon the setting of the flow control valve (32 and col. 3, lines 39-43) and inherently by the coolant selected (overlapping the claimed range of -40°C to about 20°C).

Claims 28, 32 and 38-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Milder (5,423,807). Milder discloses a cryo-therapy device and its method of use comprising:

a shaft (18) having a proximal and distal end;  
a cooling chamber (Figure 14, # 108) disposed at the distal end of the shaft defining an interior space;  
a coolant intake tube (106) disposed within the shaft and having a distal opening in fluid communication with the interior space of the cooling chamber and arranged to create a phase change in fluids (liquid to gas) introduced through the intake tube, and  
an exhaust tube (104) disposed within the shaft and having a distal opening in fluid communication with the interior space of the cooling chamber, and further comprising a thermal-resistive sensor (122) disposed proximate the cooling chamber (Figure 14 and col. 6, line 55-col. 8, line 6).

The method of use is disclosed essentially as claimed whereby the minimum temperature can be controlled to about – 10°C at the tip and thus freezing a portion of the tissue (col. 5, line 59-col. 6, line 25).

#### ***Allowable Subject Matter***

Claims 30, 31 and 36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy D. Gibson whose telephone number is 571-272-4767. The examiner can normally be reached on M-F, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Roy D. Gibson  
Primary Examiner  
Art Unit 3739

June 27, 2005